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Award Number:
W81XWH-08-2-0206

TITLE:
Utilization of Telehealth Technology to Develop and Implement a Comprehensive Management Initiative for Chronic Diseases

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REPORT DATE:
October 2009

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT:

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REPORT DOCUMENTATION PAGE		<i>Form Approved</i> <i>OMB No. 0704-0188</i>	
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1. REPORT DATE (DD-MM-YYYY) 21-10-2009		2. REPORT TYPE Annual	
4. TITLE AND SUBTITLE Utilization of Telehealth Technology to Develop and Implement a Comprehensive Management Initiative for Chronic Diseases		3. DATES COVERED (From - To) 22SEPT08 - 21SEPT09	
		5a. CONTRACT NUMBER W81XWH-08-2-0206	
		5b. GRANT NUMBER	
		5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Robert A. Vigersky, COL MC, MD Email: robert.vigersky@na.amedd.army.mil		5d. PROJECT NUMBER	
		5e. TASK NUMBER	
		5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Henry M. Jackson Foundation 1401 Rockville Pike Suite 600 Rockville, MD 20852		8. PERFORMING ORGANIZATION REPORT NUMBER 60811	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) USA Med Research and Materiel COM 504 Scott Street Fort Detrick, MD 21702-5012		10. SPONSOR/MONITOR'S ACRONYM(S) USAMRAA	
		11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release; distribution unlimited			
13. SUPPLEMENTARY NOTES			

14. Abstract - See next page.

14. ABSTRACT

Chronic diseases affect over 90 million Americans and result in high health care costs and tremendous personal and societal burden. Diabetes is, arguably, among the most pervasive and researched chronic diseases. Research shows that much of the costs and burden of diabetes can be mitigated with appropriate education, care- and self-management. This project, called the Comprehensive Management for Chronic Disease (CMICD), focuses on innovative technology approaches to improving education about and management of diabetes. The CMICD includes: virtual education techniques for training nurses (VNE); an Internet-based medical informatics tool for the management of people with diabetes called the Comprehensive Diabetes Management Program (CDMP) and its associated telehealth eye care program that can remotely evaluate eye disease without need of dilation or a specialist to conduct a live exam; a video cell phone approach to providing patients with daily, personalized reminders and education; and a computer-assisted decision support (CADS) tool that equips primary care providers with the latest clinical guidelines and specialty expertise to support their decision making about diabetes, hypertension, and hyperlipidemia. Components of the CMICD are being developed and evaluated for accuracy and usability as part of this effort (CADS), other components are being deployed and tested in rural PA in collaboration with Mt. Aloysius College (VNE and CDMP/telehealth eye care program), and others are being deployed and tested at Walter Reed Health Care System (Cell Phone). Using a variety of study designs, this project is examining both patient outcomes and providers' changes in knowledge as appropriate. Currently the CMICD focuses on the management of diabetes; however, the management approaches within the CMICD are applicable to a variety of other chronic diseases including asthma, depression, and arthritis. Currently the overall project and its components are ongoing. Thus, we do not report on major, final findings at this time; rather, this Annual Report presents progress and challenges to date as well as some preliminary findings (Cell Phone Study).

15. SUBJECT TERMS

Telemedicine, diabetes, technology, care-management, decision support, nursing education

16. SECURITY CLASSIFICATION OF: Unclassified			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 14	19a. NAME OF RESPONSIBLE PERSON Robert Vigersky
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER (include area code) 202-782-5212

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

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Introduction

Diabetes mellitus (DM) affects approximately 24 million people in the United States (Centers for Disease Control, 2005) and is associated with devastating complications in both personal and financial terms. Diabetes is the leading cause of blindness, non-traumatic amputations, and renal failure in adults and reduces life expectancy by 5-10 years. The direct (\$153 billion) and indirect (\$65 billion) costs of DM care have dramatically increased along with the epidemic increase in the number of those with DM over the past 10 years (Centers for Disease Control and Prevention, 2008; PharmaLive.com, accessed 14 January 2010). The vast majority of these costs are related to hospitalizations resulting from the chronic complications of diabetes, with only about 15% of the costs attributable to professional visits and pharmaceuticals. Much of the costs and burden of diabetes can be mitigated with appropriate education, care, and self-management. This project, a collaboration among Walter Reed Army Medical Center (WRAMC), Mount Aloysius College, and the Henry M. Jackson Foundation, is deploying and testing an innovative, technologically sophisticated program for managing and improving outcomes of diabetes. The program is called the Comprehensive Management Initiative for Chronic Disease (CMICD) and includes the following: a) virtual education techniques for training nurses (VNE); b) a video cell phone approach to providing patients with daily, personalized reminders and education; c) an Internet-based medical informatics tool for the management of people with diabetes called the Comprehensive Diabetes Management Program (CDMP) and its associated telehealth eye care program that can remotely evaluate eye disease without need of dilation or a specialist to conduct a live exam; and d) a computer-assisted decision support (CADS) tool that equips primary care providers with the latest clinical guidelines and specialty expertise to support their decision making about diabetes, hypertension, and hyperlipidemia. Components of the CMICD are being developed and evaluated for accuracy and usability as part of this effort (CADS), other components are being deployed and tested in rural PA in collaboration with Mt. Aloysius College (VNE and CDMP/telehealth eye care program), and others are being deployed and tested at Walter Reed Health Care System (Cell Phone). Using a variety of study designs, this project is examining both patient outcomes and providers' changes in knowledge as appropriate. Although the CMICD focuses on the management of diabetes, the management approaches within the CMICD are applicable to a variety of other chronic diseases including asthma, depression, and arthritis. Currently the overall project and its components are ongoing. This report describes our progress to date based on the original Statement of Work and our plans for the following year.

Body

- a. Task/objective regarding Virtual Education Techniques -- to determine whether the use of virtual education techniques can improve diabetes knowledge for practicing registered nurses as well as student nurses

The increased incidence and prevalence of diabetes in rural areas of west-central Pennsylvania, coupled with the scarcity of certified diabetes educators in this geographic location, threatens to become a major public health concern. One response to this growing crisis would be to provide continuing, high quality diabetes education for nurses who care for patients with diabetes in a variety of in-patient and out-patient settings. Such education is often less accessible to nurses who live and practice in rural areas, where distance and time present formidable barriers to educational access. Virtual diabetes education techniques that combine best educational practices with telehealth technology offer a promising solution to this problem.

Toward this task/objective, we have drafted a study protocol to evaluate the effectiveness of and satisfaction with virtual diabetes nursing education techniques compared to the effectiveness of and satisfaction with traditional, face-to-face, classroom-based diabetes nursing education. The study design is that of a quasi-experimental design (i.e., nonrandom assignment) with two groups. Specifically, traditional diabetes education for nurses taught by certified diabetes educators and clinicians and offered on-site at the Walter Reed Army Medical Center (WRAMC) will be made available in a web-based format to registered nurses

in a rural area of west-central Pennsylvania (PA). Certain lectures will also be provided via video-teleconference to facilitate communication between the students in rural PA with the instructors in Washington, DC, and to integrate the PA students into the course. Effectiveness will be measured as change (improvement) in diabetes knowledge and nursing skill as measured by pre- and post-class questionnaires. Satisfaction with the education delivery methods will be measured using validated questionnaires. One hundred and two participants will be recruited, with half receiving the in-person training and half the web-based version. Statistical analyses will reveal within and between group differences in learning outcomes and satisfaction.

Table 1 shows the progress of the protocol through the human research protections process. Once this process is complete, the study will be able to recruit study subjects.

TABLE 1. APPROVALS LOG FOR STUDY OF VIRTUAL EDUCATION TECHNIQUES				
Date	Domain	Action	Response Date	Details
6/09	WRAMC Department of Clinical Investigation	CRADA submitted	9/09	Clarifications requested and provided. <i>Still awaiting approval.</i>
7/09	WRAMC Department of Clinical Investigation	Initial submission of protocol	8/09, from Administrative and Clinical Investigation Committee responses	Clarifications and modifications requested
9/09	WRAMC Department of Clinical Investigation	Study staff responded to review		
9/09	WRAMC Department of Clinical Investigation	Human Use Committee member determined this study to be EXEMPT—exemption and approval granted 10/09		
9/09	Mount Aloysius IRB	Initial submission of protocol	10/09	Approved and determined to be EXEMPT
10/09	Office of Research Protections	Initial submission of protocols for both sites	12/17, 1/10	Questionnaire sent to study staff to help with determination exemptions status, approved as exempt
11/09	CIRO	Review of CRADA and other materials		

Notes: Shaded area indicates events that occurred beyond the reporting period for this study but before the date of this report.

Additionally, we have accomplished several technology-related tasks that are necessary for the completion of the objectives. First, we have identified a location (not at WRAMC, for a variety of reasons) for the synchronous video-teleconference between PA and DC to take place. Second, after much negotiation with several prospects, we have come to agreement with a vendor in central PA who will upload all course content to a secure web site available only to the PA students. The course content will be divided into ‘modules’ (by lecture) and will be synchronized with the “live” lectures to be delivered by the instructors.

After each module, the web site will interactively “quiz” the students on the material presented. Third, the study has completed the development of all the course content, quizzes, and pre-/post-knowledge tests for the web site and study measures. Lastly, the study has identified a vendor to videotape a “live” examination of a patient with diabetes by a Nurse Practitioner of the Diabetes Institute at WRAMC.

- b. Task/objective regarding Video Cell Phone Reminders – to determine if a video cell phone reminder system will improve compliance and glycemic control in patients with diabetes mellitus

Control of blood sugar has been shown in multiple studies to reduce the incidence of diabetes complications (Diabetes Control and Complications Trial Research Group, 1993; United Kingdom Prevention of Diabetes Study, 1998). Many people with diabetes struggle to achieve and maintain good glycemic control despite numerous new medications and technologies. There are numerous challenges to accomplishing appropriate control and various approaches to doing so.

The use of self blood glucose monitoring and techniques to improve medication compliance are among the more “non-invasive” methods that have been associated with improvement in diabetes management. Self blood glucose monitoring and medication adherence are each associated with improved glycemic control and reduction in adverse outcomes in both type 1 and in type 2 diabetes. For example, each additional blood glucose measurement results in a decrease in A1c of 0.32% (Schutt et al., 2006). Also, there is a lower rate of fatal and non-fatal cardiovascular events in those who self-monitor their blood glucose (Martin et al., 2006). With respect to medication adherence, one study found that for every 10% increment in drug adherence on a continuous scale resulted in a 0.6% improvement in A1c (Schechter et al., 2002). However, another study found that 27% of patients on 1 or more meds were non-adherent with their drug regimen, resulting in higher A1c's (Krapek et al., 2004). Despite the evidence in favor of these relatively non-invasive methods for achieving diabetes control, patient adherence to self-monitoring and medications is not consistent with providers' recommendations; e.g., 23% of patients with type 1 diabetes are non-adherent (Cramer and Pugh, 2005).

To address this, we are conducting a study in the Walter Reed Health Care System examining the clinical efficacy of video-based, diabetes/tips reminders, delivered daily via cell phone, on A1c, medication adherence, self-monitoring of blood glucose, and various psychosocial outcomes. The videos contain standardized self-care education content and last from 30 to 60 seconds. Study participants are randomized to receive the tips/reminders (we provide the cell phone and service) or to usual care. The group receiving daily tips/reminders receives videos of their own nurse practitioner from Walter Reed. The active intervention portion of the study lasts for 6 months. Subjects complete A1c tests at baseline and quarterly for one year.

Thus far, the study has obtained IRB approval (local and the Office of Research Protections) at all of the required levels as well approval of the CRADA. Moreover, 65 participants have enrolled in and completed the study. We have conducted preliminary analyses of the data for these 65 subjects. In these analyses, we found that baseline A1c at enrollment was slightly higher for the tips/reminders group (Figure 1) and age was slightly lower. This finding suggested that the test of the longitudinal effects of the intervention would need to adjust statistically for these baseline differences.

FIGURE 1. Unadjusted Summary Statistics for A1c by Group and Over Time

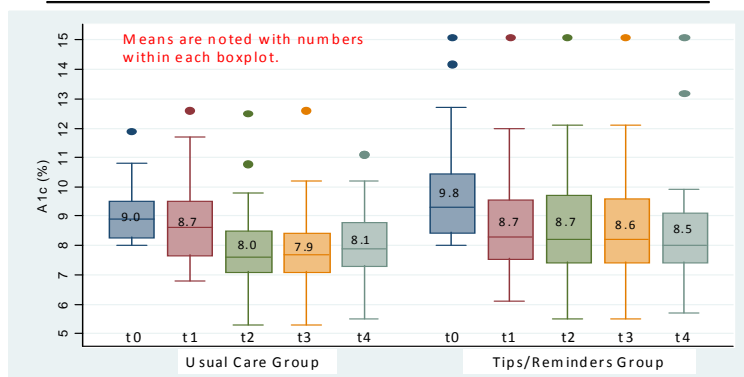
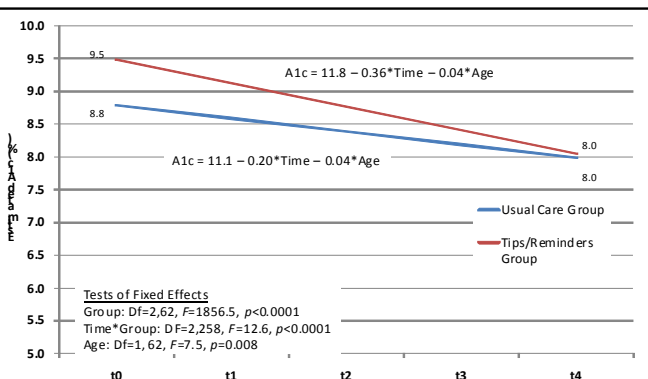


FIGURE 2. Estimated A1c Over Time, by Group



Next, in our adjusted analyses, we found that A1c for both groups improved over time and that within group change was statistically and clinically significant. Further, we found that the tips/reminders group experienced greater improvement than did the usual care group; that is, their predicted A1c dropped 1.5% whereas the predicted A1c of the usual care group dropped 0.8%.

Our next task in the upcoming year is to complete the analyses of the other study outcomes and draft a manuscript for submission to a journal.

- c. Task/objective regarding the Deployment of a Telehealth Eye Care Program in rural PA – to deploy this program in clinics in the 12th Congressional District of PA with links to a central reading station at WRAMC

Diabetic eye disease is the leading cause of blindness among working-age adults, yet it is largely preventable with timely diagnosis and treatment (Diabetic Retinopathy Study Research Group, 1981; Early Treatment Diabetic Retinopathy Research Group, 1991). Diabetes-related vision loss is often caused by a combination of poor access to and compliance with periodic eye examinations that target early detection of sight-threatening eye disease. Even in settings with little or no financial barriers to health care, compliance with periodic eye examinations is suboptimal. For example, annual compliance with eye examinations among diabetic patients is 53%, 67.7%, and 52.2% in the Indian Health Service, Department of Veterans Affairs, and the Department of Defense health care systems (Indian Health Service, 2000; Department of Veterans Affairs, 2000; Department of Defense, 2000). We suspect these rates are worse in geographical regions, such as rural PA, where access to care is more difficult.

To address this problem, we have planned to bring a telehealth eye care program to rural PA. The program was originally developed at the Beetham Eye Institute. This program and those modeled after it are well-described and validated (Aiello et al., 1998; Cavallerano AA et al., 2003; Cavallerano JD et al., 2005; Bursell et al., 2001; Chow et al., 2006). For diagnosis of diabetic retinopathy and diabetic macular edema, the telehealth eye care assessments agree substantially with mydriatic seven-standard field Early Treatment Diabetic Retinopathy Study (ETDRS) protocol photography (Bursell et al., 2001) and with dilated clinical examinations by retina specialists (Cavallerano JD et al., 2005). For diagnosis of nondiabetic eye disease among people with DM, the telehealth eye care assessments agree substantially with dilated clinical examinations by retina specialists (Chow et al., 2006). The Principal Investigator of this grant has validated the telehealth eye care program in both a single clinic and multi-clinic setting, the latter utilizing a hub-and-spoke design with cameras deployed in satellite clinics and a central reading facility at a tertiary care facility; Ahmed and colleagues have shown the telehealth eye care program to be nearly 100% sensitive and specific in the two-thirds of images that are technically capable of being graded (Ahmed et al., 2006). The telehealth diabetes eye care program has also been shown to have better diagnostic and clinical outcomes at lower costs compared to conventional clinic-based eye examinations when used to detect sight-threatening proliferative diabetic retinopathy in the Indian Health Service, the Department of Defense, and the Department of

Veterans Affairs (Whited et al., 2005). In addition to being clinically valid and cost-effective, the telehealth eye care program increased patient adherence with recommended standards of care for periodic eye examinations and follow-up treatment (Davis et al., 2003; Conlin et al., 2006; Wilson et al., 2005) and was found to be associated with decline in A1c and lipid levels over time (compared with standard care not involving the telehealth eye care program) (Fonda et al., 2007).

Toward the accomplishment of our technical objective of deploying the telehealth eye care program and testing its efficacy, we have sought to enlist clinics in PA to participate in a randomized controlled trial of the program. We attended 4 meetings, one of which was with the Medical Director of the largest health care provider in the area (Conemaugh Health System). Although initially expressing interest, physicians in that area have refused to participate. They did not agree with substituting the telehealth program for an annual dilated exam (which would be a requirement of a randomized controlled trial) and they were concerned that supporting such a program would adversely affect their revenue by taking patients away. Their refusal forced us to rethink the original research plan.

Since physicians in PA were not willing to conduct a randomized controlled trial of the telehealth eye care program, we have developed a new deployment and evaluation plan. In this plan we will have a pre-/post-test of the deployment as before, but the deployment involves participating in health fairs and weeklong screenings throughout that targeted geographical area, rather than integrating into a clinic. All people with diabetes who have no prior history of diabetic retinopathy will be eligible, and we will screen them and provide education in the public health-oriented format of the health fair. We will follow study participants over time. This approach is novel and has a public health focus. **We submitted a revised Statement of Work which has now been approved.**

FIGURE 4. Equipment for the Telehealth Eye Care Program



Further, we have thus far identified 2 local sites willing to participate in weeklong “fairs” or screenings, as well as a local collaborator to assist us. We have also identified an Ophthalmology practice in the area where we will, if necessary, be able to refer study/screening participants who are found to have diabetic retinopathy during the screening. Lastly, we have identified a contractor with the equipment and training necessary for this type of deployment (Figure 4). This was a challenge because it is still the case that most telehealth eye care programs take place in fixed locations, namely clinics.

- d. Task/objective regarding the Use of the Comprehensive Diabetes Management Program (CDMP) by Primary Care Providers – to supply providers in rural PA with CDMP, an interactive, modular, web-based care- and self-management tool for physician, care managers and patients

The CDMP is an interactive, modular, web-based tool for physicians, care managers, and patients, designed to a) provide a high level of continuous care and communication between patients, care managers, and physicians, b) draw on the latest clinical guidelines and guide care managers and physicians in following them, c) focus on patients' clinical and behavioral problem areas, and d) increase the role of the diabetes patient in the care planning process and management. Among the CDMP's modules are the Behavior Assessment Tool (BAT), which is a questionnaire designed to assess patients' barriers to effective diabetes care, and two Nutrition Assessment Tools (NAT-A and NAT-B), which are intended to assess why people eat certain ways. The CDMP also has an overall risk stratification algorithm, which uses a variety of data drawn from the patient's record (such as lab values, blood pressure readings, smoking status, whether or not the patient had a particular exam, etc.) to indicate how the patient compares to established goals in the areas of glycemic control, nephropathy, peripheral vascular disease, peripheral neuropathy, and retinopathy. The CDMP was developed after the aforementioned telehealth eye care program, because it is well-known that prevention and appropriate management of diabetic retinopathy requires good care- and self-management of diabetes overall. The telehealth eye care program is integrated into the CDMP.

As with the telehealth eye care program, the original study was proposing an evaluation of the quality of diabetes care pre- and post-implementation of the CDMP. The challenges encountered for the above apply to this project as well. Further, the change in scope approved in the revised Statement of Work applies here as well.

To review, we identified 2 local sites willing to participate in weeklong “fairs” or screenings, as well as a local collaborator to assist us with this project. As part of the screenings, we will administer the BAT and the risk stratification algorithm; the former will be applied to the educational component of the intervention and the latter will be applied to both the outcome measures and to the care plan generated from reading the teleretinal images.

- e. Task/objective regarding the Use of a Computer-Assisted Decision Support (CADS) System to improve glycemic control -- to deploy CADS to primary care providers in a pilot study as a proof-of-concept study

Due to the complexity of diabetes, its co-morbidities such as hypertension and hyperlipidemia, and the seriousness of its complications, people with diabetes are usually best monitored by highly skilled health care professionals who are equipped with the latest information to help ensure early detection and appropriate treatment and to provide diabetes education to patients. But due to a dearth of endocrinologists in both military and civilian health care settings, primary care providers (PCPs) (including family practitioners, nurse generalists and physicians' assistants) provide care to the vast majority of patients with diabetes who are not necessarily equipped with the latest information. And in a healthcare environment where a shortage of Certified Diabetes Educators exists, especially in rural areas, the burden of diabetes education often falls on staff registered nurses in hospitals, physician offices, and other healthcare facilities who may lack the expertise and/or time to provide this service. It is imperative, therefore, to give these providers the advanced technology and health information management tools to support effective care management.

To transfer this knowledge to PCPs, the Principal Investigator has developed a series of rules-based algorithms to provide decision support to primary care providers for the management of their patients with diabetes. We call it a Computer-Assisted Decision Support (CADS) System. The software allows for: download of patient self-monitored blood glucose data from memory meters to a central database; display of the data in tabular and graphical form; generation of descriptive statistics; assessment of overall level of control; and evaluation of hypoglycemia and hyperglycemia. A numerical score synthesizing all of the elements of good control is computed and presented. The software identifies a series of potential problems and prioritizes them (e.g. overnight hypoglycemia, hypoglycemia at other times of day, hyperglycemia,

excessive postprandial excursions, etc.). The programs then identify the most appropriate change(s) needed in therapy involving oral or injectable regimens for type 2 diabetes, alone or in various combinations.,. The program indicates which dose or doses of medications should be increased or decreased, when there has been ‘failure’ of a regimen to provide an adequate level of control consistent with goals for A1c and glycemic levels, and also provides recommendations for moving to another regimen.

After the first version of the CADS System was developed, we determined that we should integrate it with the CDMP so as to facilitate remote patient upload of their self-monitored blood glucose data and to provide the CADS System with as much background information about each patient as possible.

At the beginning of the funding period for this grant, the original software developer, Health Sentry, did not release the required software code to us as scheduled, seriously delaying the integration of CADS with the aforementioned CDMP. The need to integrate with CDMP means we need additional time and a Revised Statement of Work. **We have submitted this Revised Statement of Work and it has been approved.**

In a user evaluation of the CADS System by a Nurse Practitioner in our clinic, we found that the system was not yet ready for circulation to PCPs. In response, we have developed the interface more fully, we have devised an improved process for collecting the patients’ self-monitored blood glucose data, and we have created new, more user-friendly graphs of the self-monitored blood glucose data. Also, new medications for diabetes have been added to the market since the drafting of the original rules and algorithms for the CADS System, so we have expanded the application to include those. We have additionally developed new use cases, which have been discovered as part of the user feedback process. The new use cases ensure that the CADS System is more accurate and complete. Lastly, we have written a protocol for a full testing of the application (to be performed under separate funding) and developed a Technical Assessment Questionnaire to be administered to providers using the application.

The CADS will now undergo further usability testing, continued integration with the CDMP, and refinement as needed. Per the Revised Statement of Work, the outstanding deliverable is now a vetted (with respect to usability and accuracy) CADS System.

Key Research Accomplishments

Virtual Education Techniques:

- Completed construction of computer and video-teleconferencing lab at Mount Aloysius
- Scheduled the workshop events (2)
- Completed protocol draft and submitted to IRB
- Completed workshop agenda at Walter Reed
- Developing interactive web site for all of the course content and quizzes

Video Cell Phone Tips/Reminders:

- Created an extensive library of videos
- Drafted protocol, submitted it to the IRB, and received approval
- Recruited 65 subjects
- Conducted preliminary analyses with the main outcome – A1c

Telehealth Eye Care Program and Comprehensive Diabetes Management Program:

- Met with health care providers and Medical Directors to enlist clinics to participate – which led to rethinking the methodology
- Contracted to buy the equipment needed

- Identified local champions
- Identified and enlisted local sites for a public health-type “fair” or screening
- Established the new methodology by which we will conduct the study
- Drafted a protocol

Computer-Assisted Decision Support System:

- Developed the interface and how we are going to collect the data so that the application can perform its tasks
- Through user feedback process, discovered/developed additional use cases
- Developed a Technical Assessment Questionnaire to be administered to providers observing the application
- Wrote a protocol for a full test under new funding
- Created new and improved graphs of the self-monitored blood sugar data

Reportable Outcomes

The following are presentations we have given to date in the funding period:

- Vigersky R, Bell A, Fonda S, Sami S, Walker S, Schmidt V. Using cell phone reminders in diabetes mellitus. Abstract. *Telemedicine and e-Health* 2009; 15: S31.

The following are projects that we have applied for funds to support. Aspects of these projects have grown out of what we have learned conducting this project. In brief, the projects will:

- Develop and study a Personal Health Record Application (PHR-A) that captures information about daily living important for diabetes & provides decision support with actionable advice for diabetes self-care
- Develop a self administered stereo non mydriatic automated retinal camera (SNARC) containing automated retinal lesion (ARL) detection using adaptive optics
- Study the use of a Computer-Assisted Decision Support (CADS) system to improve outcomes in patients with Type 2 Diabetes who are treated by Primary Care Providers.

Conclusion

The CMICD is an ongoing, multi-project effort and as yet we do not have final research and development results to report. However, we believe that the projects herein have the potential to address and/or prevent the serious complications of diabetes, even in geographical regions or socioeconomic settings where access to diabetes education and/or care are limited. One such project can reduce or prevent complications through the use of diabetes tips and reminders sent via a relatively low-cost, ubiquitous and familiar tool, the cell phone. Another project can do so through the combination of telemedicine technologies and public health-based education to provide a quick, convenient, and low-cost evaluation for diabetic retinopathy. The evaluation for diabetic retinopathy can then lead to a care management plan based in best practices guidelines, using our medical informatics tool, the CDMP. Yet another project can mitigate diabetes complications with the development and distribution of diabetes expertise – as computer-assisted decision support – to providers who are generalists and/or do not have the time to stay apprised of the many and varied drug regimens for diabetes management. Finally, with the CMICD, nurses in rural areas who care for patients with diabetes but do not have access to or time-flexibility for diabetes-specific continuing education can now receive this education through the Internet, at their own pace and while continuing to work. Although the content of the tips, decision support, education, and clinical guidelines is all about diabetes, the approaches here can easily be applied to other chronic diseases.

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Appendices

None